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09/673,139	06/12/2001	Peter Allen Revell	23530-0003	9561

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EXAMINER

ROBERT, EDUARDO C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/673,139

Applicant(s)

REVELL ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Objections*

Claims 6-14 are objected to because of the following informalities: In claims 6-14, line 1, "A bone" should be changed to -- The bone --. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 applicants appear to recite a method step of making the bone implant, i.e. "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition" and this is indefinite because the general rule is that a product claim violates 35 USC 112, second paragraph, if structure is described by the process of making rather than in structural terms and the structure is capable of description in structural terms. *In re Johnson*, 157 USPQ 106 (CCPA 1974).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

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USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "metal or metal alloy", and the claim also recites "preferably a titanium alloy" which is the narrower statement of the range/limitation.

Claims 20 is directed to "The method as claimed" in claim 14, however claim 14 is directed to a bone implant. It appears that claim 20 should be depended from claim 15 instead of claim 14 and will be considered as such for examination purposes.

Claim 21 is directed to "The method as claimed" in claim 14, however, claim 14 is directed to a bone implant. It appears that claim 20 should be depended from claim 15 instead of claim 14 and will be considered as such for examination purposes.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

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section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 7-9, 11-16, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz (Reference "B" on PTO-1449).

Constantz discloses an implant having a hydroxyapatite coating that the coating can have incorporated therein a variety of ions, as required (see col. 2, lines 64-68). With regard to the method step recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition", it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not given patentable weight. It is noted that the ions comprise fluorine ions.

Claims 1, 2, 7-16, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Natasi, et al.

Natasi, et al. disclose an implant having a hydroxyapatite coating that the coating can have incorporated therein a ion (see abstract). Natasi, et al. disclose that any ions might be utilized in the ion implantation process (see col. 5, lines 25-27), thus this statement include ions of groups IIA, IVA, VIIA and transition elements. With regard to the method step recitation in claim 1, "the ions are incorporated into or onto the surface of the bone implant by ion beam implantation or cathodic arc deposition", it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not given patentable weight. However, it is noted that Natasi, et al. disclose that the ions are incorporated via ion beam implantation.

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Applicant is reminded that an anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data System, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). Furthermore, it is well settled that the law of anticipation does not required that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e. all limitation of the claims are found in the reference. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6, 10, 17-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (Reference "B" on PTO-1449).

Constantz discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm (claims 3 and 17), or up to a maximum

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depth of 150 nm (claims 4 and 18), or up to a maximum depth ranging up to approximately 100 nm (claims 5 and 19), or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface (claims 6 and 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct implant disclosed by Constantz with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, or up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claims 10 and 24, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant disclosed by Constantz with the ions being magnesium, manganese, zinc, or silicon ions, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 3-6 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nastasi, et al.

Nastasi, et al. discloses the claimed invention except for the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm (claims 3 and 17), or up to a maximum depth of 150 nm (claims 4 and 18), or up to a maximum depth ranging up to approximately 100 nm (claims 5 and 19), or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface (claims 6 and 20). It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to construct implant disclosed by Nastasi, et al. with the ions being incorporated into the surface of the implant up to a maximum depth of 200 nm, or up to a maximum depth of 150 nm, or up to a maximum depth ranging up to approximately 100 nm, or the ions being presented at a level between  $1 \times 10^{10}$  and  $1 \times 10^{18}$  ions per  $\text{cm}^2$  of the surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Constantz, et al. is a cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333.

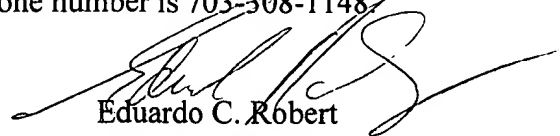
The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C. Robert  
May 3, 2002